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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,067	01/12/2001	Vladimir Puskaric	P04821US0 PHI 1313	2599

27310 7590 08/07/2002
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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,067

Applicant(s)

PUSKARIC, VLADIMIR

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

1. The specification is objected to for the inclusion of blank lines, on page 7 in the bottom paragraph.

Claim Objections

2. Claims 6, 12, 16, 25, and 29 are objected to. In line 1 of the claims, "A" should be --The-

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,156,958 ('958). Although the conflicting claims are not identical, they are not patentably distinct from each other because

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they both appear to be drawn to the same maize seeds, plants, plant parts and methods. The instantly claimed plants and the patented plants have different designations. The designation "39K40" of the instantly claimed cultivar is arbitrarily assigned, and does not provide any patentable distinction from the cultivar claimed in '958, "33J24." Any differences between 39K40 and 33J24 are due to minor morphological variations that do not confer patentable distinction. The instantly claimed maize plants that have as at least one ancestor 39K40, or 39K40 containing one or more transgenes, or 39K40 containing one or more genes transferred by backcrossing, or maize plants having all the morphological and physiological characteristics of 39K40 and is further male sterile, would then be encompassed by the patented maize lines derived from 33J24, or 33J24 containing one or more transgenes, or 33J24 containing one or more genes transferred by backcrossing, or maize plants having all the morphological and physiological characteristics of 39K40 and is further male sterile. As 39K40 and 33J24 are not patentably distinct, the claimed methods that comprise their use are obviously the same as well. A patent issuing from the instant application would then effectively extend the patent term of the claims of '958.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The recitation "39K40" in claims 1, 5, 7, 11, 15, 19, 24, 28, and 32 render the claims and those dependent thereon indefinite. Since the name "39K40" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "39K40" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and the specific characteristics associated therewith could be modified. The missing ATCC accession number in claims 1, 5, and 7 similarly also renders the claims indefinite, as the claims do not clearly identify the deposited seed. Amending claims 1, 5, and 7 to recite the ATCC deposit number in which hybrid maize seed 39K40 has been deposited would overcome the rejection.

In claims 11, 15, 19, 24, 28, and 32: the terms "very high," "very good," and "suited" are relative terms that have no definite meaning. The terms do not reasonably apprise one of the scope of the invention. It is also not clear what kind of yield (grain, silage, pollen, etc.) is referred to by "very high yield." The recitation "Northwest, Northcentral, and Northeast regions of the United States and to Canada" also renders the claims indefinite. It is not exactly clear what states or geographic areas make up these regions.

In claims 10, 14, 18, 23, 27, and 31: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the corn plant breeding program of claims 9, 13, 17, 22, 26, and 30, respectively. However, claims 9, 13, 17, 22, 26, and 30 are directed to methods, not programs. It is suggested that the recitation "corn plant breeding program" in line 1 of claims 10, 14, 18, 23, 27, and 31 be replaced with --method--.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8, 11-19, 21, and 24-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any hybrid maize seed designated 39K40, wherein said plant is male sterile; or any maize plant or its parts wherein at least one ancestor is 39K40 and expresses a combination of at least two 39K40 traits; or a hybrid maize plant grown from seed of 39K40, or which has all the morphological and physiological traits as the plant grown from 39K40 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more transgenes and which expresses at least 2 39K40 traits; or a hybrid maize plant grown from 39K40 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least 2 39K40 traits.

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The specification describes morphological and physiological traits of a hybrid maize plant grown from hybrid maize seed arbitrarily designated "39K40", which was produced by crossing two inbred lines designated "GE535658" and "GE516223" (page 7, last paragraph; page 17; Table 1, pages 18-20). The specification also describes comparisons of 39K40 to other hybrid plants (pages 21, Tables 2A-2C on pages 22-24, page 25, Table 3 on page 26, page 27, first paragraph and Table 4). The specification further indicates that upon allowance of any claims, all restrictions on the availability to a deposit of 2500 seeds of 39K40 with the American Type Culture Collection will be removed, that the deposit will be maintained without restriction, that all requirements of 37 CFR 1.801-1.809 will be met, and that the deposit will follow the requirements of 37 CFR 1.801-1.809 (page 42).

However, the specification does not describe 39K40 as being male sterile. The specification discusses how plants may be manipulated to become male sterile (paragraph bridging pages 2 and 3 and the first full paragraph of page 3). However, the morphological and physiological description of plant 39K40 in the specification does not indicate that it is male sterile.

The specification also does not describe the plants developed by the maize breeding programs, transgenic 39K40 plants, 39K40 plants further comprising genes transferred by backcrossing, or maize plants wherein at least one ancestor is corn variety 39K40 and which express at least two of the traits listed in claims 11, 15, 19, 24, 28, or 32. The morphological and physiological traits of the corn plants that are crossed with 39K40, and with progeny of that cross, are unknown, and the description of progeny and descendants of corn plant 39K40 are unknown. The description of corn plant 39K40 is not indicative of any of its descendants. To

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say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by 39K40. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant 39K40. For example, Segebart (U. S. Patent No. 6,156,958) describes a corn plant designated "33J24," which has at least two traits in common with 39K40, very high yield and very good stalk quality, for example (col. 12, lines 4-6). The instantly claimed corn plants could have 33J24 as an ancestor, as well as 39K40, in which case the yield potential and stalk strength traits, for example, could have been inherited from 33J24. Further, it is not known what genes of 39K40 would be affected in the claimed methods comprising breeding programs. The traits of the plants produced by the programs are unknown, and are not described by the specification. The transgenes, and genes introduced into 39K40 by backcrossing, may be of gene(s) that effect any trait or more than one trait. Such plants would express different morphological and physiological traits from 39K40, and which are not described. Given the breadth of the claims encompassing corn plant 39K40 having male sterility, corn plants expressing at least two traits that are also expressed by 39K40, any transgenic 39K40 plant, any 39K40 plant further having any gene(s) introduced by backcrossing, methods comprising the use of such plants, lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

6. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards hybrid maize seed designated "39K40"; a corn plant produced by growing seed of any hybrid maize seed designated 39K40, or parts thereof; or wherein said plant is male sterile; or any maize plant or its parts wherein at least one ancestor is 39K40 and expresses a combination of at least two 39K40 traits; or a hybrid maize plant grown from seed of 39K40, or which has all the morphological and physiological traits as the plant grown from 39K40 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more transgenes and which expresses at least 2 39K40 traits; or a hybrid maize plant grown from 39K40 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least 2 39K40 traits.

Since the claimed seed of maize hybrid line 39K40 is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily

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available to the public. Applicant's intent to deposit the seed with the ATCC is acknowledged (page 42).

If the seeds are deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

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Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (e) the invention was described in-
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Segebart (U.S. Patent No. 6,156,958).

The claims are broadly drawn towards hybrid maize seed designated "39K40"; a corn plant produced by growing seed of any hybrid maize seed designated 39K40, or parts thereof; or wherein said plant is male sterile; or any maize plant or its parts wherein at least one ancestor is 39K40 and expresses a combination of at least two 39K40 traits; or a hybrid maize plant grown from seed of 39K40, or which has all the morphological and physiological traits as the plant grown from 39K40 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize

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plant comprising one or more transgenes and which expresses at least 2 39K40 traits; or a hybrid maize plant grown from 39K40 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least 2 39K40 traits.

Segebart teaches seed of a hybrid maize line designated "33J24," plants produced by growing said seed, and plants and plant parts, including pollen and ovules (col. 12, lines 4- 19, Table 1; col. 15, line 45 to col. 23, line 42, Tables 2A-2E; Tables 3 and 4; col. 25, lines 3-7 and col. 26, lines 1-7; claims). It appears that the claimed plants and seeds of the instant invention may be the same as 33J24, given that they exhibit similar traits, such as very high yield and very good stalks, for example (col. 12, lines 4-6). Alternatively, if the claimed plants, plant parts, and seeds of 39K40 are not identical to 33J24, then it appears that 33J24 only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 39K40. Segebart also teaches methods to confer male sterility to corn plants, and assert that large-scale commercial maize hybrid production require the use of some form of male sterility, and that a reliable method of controlling male fertility in plants also offers the opportunity for improved plant breeding (col. 1, line 53 to col. 2, line 60). It would have been obvious and within the scope of one of ordinary skill in the art to make plant 33J24 male sterile,

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following one of the methods taught by Segebart. One would have been motivated to make 33J24 male sterile, given its requirement for hybrid production and importance for improved plant breeding, as taught by Segebart. Segebart also teaches production of tissue culture of regenerable cells from a plant of line 33J24, wherein regenerable cells are from tissues including flowers, pollen, ovules, among others; a plant produced from tissue culture of 33J24 that is capable of expressing all of the morphological and physiological traits of 33J24; corn plant breeding programs, including backcrossing, pedigree breeding, recurrent selection, among others; maize lines derived from 33J24, or from 33626 containing one or more transgenes, or from 33J24 containing one or more genes transferred by backcrossing; use of backcrossing to introduce gene(s) for desirable traits; 33J24 comprising at least one transgene, and using the plant in maize breeding programs; maize plants produced by those breeding programs, 33J24 comprising genes(s) introduced by backcrossing, and use of the plant in a method for developing a plant for breeding programs (col. 2, line 61 to col. 5, line 59; col. 25, lines 33-67; col. 26, line 31 to col. 35, line 42; claims). The claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Segebart.

8. No claim is allowed.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to

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reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

July 15, 2002